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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,377	07/11/2003	William C. Biddle	0942.4600003	2241

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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,377	BIDDLE ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/11/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-7; as well as, the single species of adventitious agents or toxins of animal viruses as recited in Claim 8, which reads on Claims 1-8, 10-13 and 15-27 on the elected species of adventitious agent; as well as the single species of sample or animal culture medium, which reads on Claims 1-18, 20 and 27 on the elected species of sample, in the reply filed on July 27, 2006 is acknowledged.

Claim 28 is withdrawn fro further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse on July 27, 2006.

Claims 1-27 are under examination.

The claims have been examined insofar as they read on the elected species.

Claim Objections

Claims 1, 24 and 24 are objected to for the following informality:

An apparent typographical error appears in Claim 1, line 4, wherein it appears that Applicant has omitted a conjunction to connect the phrases.

An apparent misspelling appears in Claim 24, line 2. Applicant may overcome the objection by replacing "ore" with more.

An apparent typographical error also appears in Claim 24, at the end of line 4 bridging line 5. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 57152882 (AM2), as evidenced by the teachings of Maeda et al. (AL3, EP 0049632); Williams (AF3, US 4,072,570); Noguchi et al. (P, JP 04198137); Downes et al. (Downes, T. E. H. et al., (1987). Suid Afrikaanse Tydskrif Vir Veekunde (AT, S. Afr. J. Anim. Soc.), 17(2): 55-58.); and, Pisecky et al. (AA2, US 4,490,403).

Applicant claims a method for reducing adventitious agents or toxins in a sample comprising: a) exposing a sample to air or gas or combination of gases under conditions sufficient to reduce or more adventitious agents, or one or more toxins in the sample; and b) obtaining the sample.

JP 57152882 teaches that live microbes on chlorella may be sterilized by conveying chlorella slurry, wherein the slurry is withdrawn from culture pond or slurry produced by adding water to chlorella powder and mixing and stirring to adjust solid content to 5-30 weight % at quantitative rate under pressure of 0.5 kg/cm2 – 7kg/cm2 into steam-liquid mixer and introducing stem at quantitative rate under pressure of 1.5-8 kg/ cm2 to mix steam and chlorella slurry after mixing to 100-150 degree C, pressure 0.5 kg/ cm2 – 6 kg/cm2 for 1-60 seconds and centrifugal spray-drying to sterilize and dry at the same time. Chlorella in slurry may be maintained at high temperature and

high pressure instantaneously before centrifugal spray-drying and dried quickly to carry out sterilization and drying out at the same time without deterioration. Given the broadest breadth of interpretation of the claims, the "sample" obtained and taught by JP 57152882 reads on "bacterial culture medium, plant culture medium, and animal culture medium", as well as "a pharmaceutical composition" because the sterilized, spray-dried chlorella taught by JP 57152882 can be used in the culturing of cell cultures, *e.g.*, as evidenced by the teachings of Maeda.

Williams teaches a method of spray-drying liquid Lowenstein-Jensen medium to obtain a stabilized dry powdered medium which can be stored for an extended period of time without deterioration. Although Williams does not expressly teach his method of making a spray-dried medium as a method to reduce adventitious agents or toxins in a sample, the method taught by Williams is the same or essentially the same as disclosed and/or instantly claimed by Williams. For instance, Williams teaches spray-drying the bacterial culture medium in a spray dryer at an inlet temperature of between 230°-280°F (110°-138°C) and an outlet temperature of between 160°-190°F (71°-88°C), which are the same experimental parameters of temperature disclosed by Applicant at [0102] of the present application. Thus, a method for reducing adventitious agents or toxins in bacterial culture media is inherent to the method of making the spray-dried Lowenstein-Jensen culture media taught by Williams.

On page 55, Column 2, lines 7-16, Downes teaches a method of reducing bacteria and viruses in the processing of a sterilized blood meal (an animal culture media) comprising whey protein to ultrafiltration and spray drying to obtain a spray-dried

protein concentrate, and spray drying blood at an air inlet temperature of 160°C and an outlet temperature of 80°C. Gamma irradiation of the spray-dried blood was effective in killing both virus plaque-forming (*i.e.*, Bluetongue virus and Banzi virus) and bacteria. See Table 2 and page 56, Column 2, line 30 to page 57, line 7. Given the broadest interpretation of the claim, the sterilized blood meal taught by Downes is read an "animal culture media" because the spray-dried blood meal taught by Downes can be used in the culturing or the growth of an "animal cell", *e.g.*, as evidenced by the teachings of Downes. Although Downes does not expressly teach his method of making blood meal as a method of reducing one or more toxins, a method for reducing one ore more toxins is inherent to the processing of blood meal taught by Downes because the experimental parameters of temperature taught by Downes are the same or essentially the same disclosed by Applicant at [0102] of the present application. Moreover, Downes teaches his blood meal sample as a sterilized blood meal.

Pisecky teaches a process of making an agglomerated powdery milk sample, which is fit for food and fodder consumption. Liquid milk or whey is prayed into a stream of dry gas air at 200°C-400°C to form agglomerated powder particles, which are further dried. Given the broadest breadth of interpretation of the claims, the agglomerated powdery powder particles, the agglomerated powdery milk product taught by Pisecky is read as "animal culture media" because the referenced samples can be used in the culturing of animals. Although Pisecky does not expressly teach his method of making agglomerated milk powder as a method of reducing one or more adventitious agents, such as toxins, viruses and pathogenic microorganisms is inherent to the

processing of agglomerating milk powder taught by Pisecky because the experimental parameters of temperature taught by Pisecky are the same or essentially the same as disclosed by Applicant.

The references anticipate the claimed subject matter.

Claims 1-21 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by the American Protein Corporation (AS.

American Protein Corporation manufactures a packaged nutritive medium powder which is safe use in animal feeds (read herein as an animal culture medium). The American Protein Corporation teaches a method of spray-drying bovine blood and milk proteins to produce a powder free of viruses because of three factors: 1) during spray-drying, liquid plasma is aerosolized by a sheer force of 25,000 x g which disrupts envelope viruses (which are capable of causing acute or chronic disease or toxicity), 2) the aerosols are subjected to a temperature of 400°C which inactivate viruses, and 3) the desiccation of the aerosol droplets further participates in the inactivation of viruses.

The reference anticipates the claimed subject matter.

Claims 1-4, 8-14, 18-21 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lea (AP1, WO 98/15297).

Lea teaches a gas-dispersing apparatus and process to reduce adventitious agents, such as viruses, bacteria, and fungi present in any liquid containing a buffered solution, *e.g.*, immunoglobulins in phosphate-buffered saline for use in tissue culture

systems. He directs his teachings to reducing adventitious agents in blood or blood-derived products, such as serum albumin, clotting factor, plasmin, and fibrinogen by exposing a biological sample with singlet oxygen or ozone. Moreover, Lea teaches that the referenced method is useful for reducing adventitious agents present in other biological liquid containing proteins, such as cell culture fluid, liquid nutrient fluid, or liquid nutrient extract, e.g., Bovine Pituitary Extract and any type of blood cell.

The reference anticipates the claimed subject matter.

Claims 1-22 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Robey et al. (AT, In Vitro, 34(3), Part II, V-1007. A comparison of the effects of powdered and liquid fetal bovine serum on normal human cell growth, metabolism and urokinase formation.) and Camire et al. (AR, In Vitro, 34(3), Part II, V-1008, (.3/1998). Efficient cultivation of cells using powdered serum.) and, as evidenced by the teachings of Downes et al. (AT).

Robey teaches a spray-dry process for making powdered fetal bovine serum from a liquid and the use of powdered fetal bovine serum as a nutritive medium supplement to support human cell growth, metabolism and urokinase formation in culture.

Camire teaches a process to produce bovine serum by a spray-dry process and the use of the powdered sample as a nutritive medium supplement in basal medium to culture hybridoma and Vero cell lines.

Neither Robey nor Camire expressly teaches either of the referenced methods as a method for reducing adventitious agents or toxins in a sample. However, it is inherent that adventitious agents or toxins are reduced in the process taught by either Camire or Robey because Downes, as set forth above, teaches that the heat of a spray-drying method reduces the numbers of bacteria and inactivates viruses present in a blood-derived sample.

The references anticipate the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
October 16, 2006